K080583

JUL 18 2008

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

General Information

Trade Name	Modified HD Guide Catheter
Common Name	Percutaneous Catheter
Classification	Percutaneous Catheter, 21CFR 870.1250 – Class II
Submitter	Concentric® Medical, Inc. 301 E. Evelyn Avenue Mountain View, CA 94041 Tel 650-938-2100 Fax 650-938-2700
Contact	Laraine Pangelina Director, Regulatory Affairs

Intended Use

The Modified HD Guide Catheter is indicated for use in facilitating the insertion and guidance of an occlusion catheter, infusion catheter or other appropriate microcatheter into a selected blood vessel in the peripheral, coronary or neuro vascular systems. It may also be used as a diagnostic angiographic catheter.

Predicate Device

Concentric HD Guide Catheter, K003880

Device Description

The Modified HD Guide Catheter is a single-lumen, braided shaft, variable stiffness catheter with a radiopaque marker on the distal end and a luer hub on the proximal end. The catheter shaft has a hydrophilic coating to reduce friction during use. The radiopaque shaft and distal marker facilitate fluoroscopic visualization. Device dimensions and configuration are shown on the product label. A rotating hemostatic valve with side-arm adapter is provided with each catheter.

Materials

All materials used in the manufacture of the Modified HD Guide Catheter are suitable for the intended use of the device and have been used in numerous previously cleared products.

Testing Summary

The results of verification and validation conducted on the Modified HD Guide Catheter demonstrate that it performs as designed and is suitable for its intended use.

Summary of Substantial Equivalence

The Modified HD Guide Catheter is substantially equivalent to the predicate device with regard to device design, intended use, patient population and anatomical site. Any differences in technological characteristics between the Modified HD Guide Catheter and the predicate device do not raise any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 18 2008

Concentric Medical Inc
c/o Ms. Laraine Pangelina
Director, Regulatory Affairs
301 East Evelyn Avenue
Mountain View, CA

Re: K080583
~~Trade/Device Name: Modified HD Guide Catheter~~
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: July 7, 2008
~~Received:~~ July 15, 2008

Dear Ms. Pangelina:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, ~~please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket~~ Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known):	This application K080583
Device Name:	Modified HD Guide Catheter
Indications for Use:	The Modified HD Guide Catheter is indicated for use in facilitating the insertion and guidance of an occlusion catheter, infusion catheter or other appropriate microcatheter into a selected blood vessel in the peripheral, coronary or neuro vascular systems. It may also be used as a diagnostic angiographic catheter.

Prescription Use X (Per 21 CFR 801.109) AND/OR Over-The-Counter Use_____ (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachon

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K080583